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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/517,468

12/06/2004

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KUZ-0021

1362

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11/20/2009

EXAMINER

PALENIK, JEFFREY T

ART UNIT

PAPER NUMBER

1615

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/517,468	<b>Applicant(s)</b> SUZUKI ET AL.	
	<b>Examiner</b> Jeffrey T. Palenik	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 3-14 and 16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3-14 and 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

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## **DETAILED ACTION**

### **STATUS OF THE APPLICATION**

Receipt is acknowledged of Applicants' Amendments and Remarks filed, filed 29 July 2009, in the matter of Application N° 10/517,468. Said filings are entered on the record. The Examiner further acknowledges the following:

Claim 3 is amended to reflect a narrower thickness for the polyester-based film (e.g. 5-25 microns). Claim 16 is newly added and reflects an even narrower thickness range for the PE-based film. Both claims are supported by the instant claims and original disclosure.

Claim 15 is newly cancelled.

No new matter has been added.

Thus, independent claim 13 and dependent claims 3-12, 14 and 16 now represent all claims currently under consideration.

### **INFORMATION DISCLOSURE STATEMENT**

No new Information Disclosure Statements (IDS) have been filed for consideration.

### **MAINTAINED REJECTIONS**

The following rejections are maintained from the previous Office Correspondence dated 11 May 2009 since the art which was previously cited continues to read on the amended limitations.

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### **CLAIM REJECTIONS - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 13, 5, 9, 10 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Chono et al. (USPN 6,139,866) and Tomaru et al. (USPN 6,563,195).

Newly added independent claim 13 is drawn to a patch comprising a polyester-based film and a drug-containing adhesive layer, wherein the adhesive-contact side of the polyester film has

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a surface roughness ranging from 0.05-0.8 microns and wherein the film contains no pinholes.

Claim 5 recites that the polyester-based film is polyethylene terephthalate (PET). Claim 9 recites that the area of the composition of claim 13 ranges from 5-60 cm<sup>2</sup>. With regard to the limitation recited in claim 10, which states “the bending stiffness of a substrate is from 10-80 mm”; until some material difference in the properties of the composition is demonstrated, said limitation is considered by the Examiner to be directed toward the polyester-based substrate, which is instantly claimed. Claim 14 recites that the polyester-based film “is sandblasted” prior to being contacted with the drug-loaded adhesive layer. Said limitation is interpreted by the Examiner as a product-by-process limitation (MPEP §2113) which states that even though the claim is limited by and defined by the process, determination of patentability is based on the product itself.

Chono et al. expressly teach a percutaneous tape formulation comprising a drug which is immersed within an adhesive layer (claim 1), which may then be applied to a 30-micron PET film (Example 2). The teachings of Chono are further silent to the presence of “pinholes” in the PET film layer, which is interpreted by the Examiner as the film layer being free of said pinholes.

Chono neither expressly teaches the instantly claimed PET film as having a surface roughness ranging from 0.05-0.8 microns on the side which contacts the adhesive layer nor the instantly claimed area limitation.

Tomaru et al. teach preparing a base sheet by “blasting” it in order to achieve a textured surface, to which is adhered a silicone rubber layer having substantially uniform thickness (col. 2, lines 17-24). The base sheet is taught as being a film of uniform thickness, advantageously

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prepared from polyethylene terephthalate (PET) and having a thickness ranging from 25 to 1,000 microns (col. 3, lines 49-57). It is further taught that if the film is too thin then it lacks the desired stiffness, whereas if it is too thick, then it becomes difficult to work with (col. 3, lines 54-59). Lastly, the surface roughness imposed on the film is taught as ranging preferably from 0.3-2.0 microns. Example 1, in particular, expressly teaches blasting a PET film in order to achieve a surface roughness ( $R_a$ ) of 0.8 microns after which the silicone rubber layer is directly applied.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to have polished or “blasted” the polyester-based film of Chono to the desired surface roughness prior to the application of an additional layer, particularly one with adherent properties because to do so advantageously increases the interlayer friction. The ordinarily skilled artisan would have been particularly motivated to do so because polishing a PET film as taught by Tomaru not only inherently teaches that the surface area to which the adherent layer is applied is increased, but more critically, it teaches that the layer which is applied after blasting is more securely adhered to the film, thereby reducing overall slippage between the two layers (col. 1, lines 45-52 and col. 3, lines 29-40).

Furthermore, regarding Applicants’ instantly claimed area range, it is noted by the Examiner that the value or format of a parameter (e.g. area of a patch) with respect to the claimed composition is adjustable. It thus follows that adjusting the size of such a patch formulation is a result-effective parameter that a person having ordinary skill in the art would be motivated to easily and routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. For example, Example 1 of

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Tomaru teaches that the blasted and layered PET base film is 400 mm or 40 cm wide. Though, the length of the film is not expressly discussed, it would have been customary for an artisan of ordinary skill, to adjust the length of said film in order to achieve a patch having an area such as that which is instantly claimed. Thus, absent some demonstration of unexpected results from the claimed parameters, optimization of any of these parameters would have been obvious at the time of Applicants' invention.

Based on the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, alone or in combination, especially in the absence of evidence to the contrary.

Claims 3, 4, 6-9, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chono et al. with respect to new independent claim 13, as set forth above.

Claim 13 is drawn to a patch comprising a textured, polyester-based film and a drug-containing adhesive layer, as discussed above.

Claim 3 recites that the thickness of the polyester-based substrate ranges from 5-40 microns, whereas claim 4 recites an adhesive layer thickness ranging from 50-125 microns. These limitations are expressly taught by Example 2 which teaches the application of a 100-micron adhesive layer mixture to a 30-micron PET film.

Claims 6 recites that the adhesive layer comprises the block copolymer styrene-isoprene-styrene (SIS). Claim 7 recites that the adhesive layer comprises both SIS copolymer as well as

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polyisobutylene (PIB). Claim 8 recites that the adhesive layer further comprises a tackifier, a plasticizer, or both. Claims 11 and 12 recite that the drug contained by the adhesive layer is a narcotic analgesic such as fentanyl or a fentanyl salt. These limitations are also expressly taught by Example 2, wherein the mixture applied to the PET film comprises both SIS block copolymer and polyisobutylene, polyterpene resin tackifier, as well as fentanyl citrate.

### **RESPONSE TO ARGUMENTS**

Applicants' arguments with regard to the rejection of claims 13, 5, 9, 10 and 14 under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Chono et al. and Tomaru et al., as well as the rejection of claims 3, 4, 6-9, 11 and 12 under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Chono et al., have both been fully considered but neither are persuasive.

Applicants argue that the rejection of claim 13 over combined teachings of Chono and Tomaru does not constitute an obviousness rejection primarily because the Tomaru reference is directed to a different field of invention per MPEP §2141.01(a), essentially arguing Tomaru as non-analogous art.

In response, the Examiner respectfully disagrees and maintains that the Tomaru reference is more broadly relied upon for its teachings with respect to the modification of and properties of polyethylene terephthalate films. The Tomaru reference, as discussed above, provides a teaching for modifying polyester-based films to increase their ability to "anchor" themselves to a given substrate, adhesive or otherwise, and in the absence of using pinholes to do so. Tomaru teaches that it is particularly advantageous to alter the texture of the surface of a PET film in order to



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increase the peel strength required to remove said polyester film (col. 3, lines 30-60). The Examiner is well aware that this is not an expressly recited limitation in Applicants' claims. However, the concept still remains that the PET film which is taught as having an adjustable surface roughness will similarly have an adjustable amount of area which is in contact with layer to which it is attached. The more area which is on contact, the greater the amount of friction between the two layers and thus the greater amount of force or peel strength required to pull them apart. Thus, since the Tomaru reference teaches and suggests these advantages to modifying a polyester film for the purposes of increasing its tack to a given surface, it is the position of the Examiner that though the inventive technologies diverge, the broader applicable concepts and reasons for physically modifying a film layer are analogous and would have commended itself to the inventors' attention in considering the invention as a whole, particularly at the time the invention was made.

Regarding Applicants' amended thickness limitation in claim 3 (e.g. 5-25 microns), the Examiner continues to consider the combined teachings as reading on said limitation. Firstly, absent a showing of evidence to the contrary, said thickness appears to be a parameter which may be optimized by the ordinarily skilled artisan. Secondly, and more importantly, the combined references teach and suggest that a film thickness of 25 microns may be used.

Thus, for these reasons, Applicants' arguments are found unpersuasive. Said rejection is therefore **maintained**.

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### NEW REJECTIONS

In light of Applicants' newly added claim 16, the following rejection has been newly added:

### CLAIM REJECTIONS - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Chono et al. and Tomaru et al. as set forth above with respect to claim 13 in combination with Nakahara et al. (provided as an English machine translation of JP 06-287134).

The combined teachings of Chono and Tomaru are discussed above. However, neither teaches the use of a polyethylene terephthalate (PET) film having a thickness of 5-10 microns for the purposes of a layered bandage. Of particular note is that Tomaru expressly teaches that when the film used is too thin, it lacks the stiffness required for a produced sheet. However, Tomaru does not specify what this lower limit of thickness is.

Nakahara expressly teaches adhesive skin plasters which comprise not only a medicated, SIS block copolymer adhesive layer, but one which is in direct contact with a laminate layer formed from polyethylene terephthalate (Abstract; claims). Said laminate layer is expressly taught as having a thickness of 10 microns or less.

Thus, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to have prepared the instantly claimed patch composition using a PET-film layer having thickness as instantly claimed. The ordinarily skilled artisan would have been particularly motivated by the teachings of Nakahara which disclose that the layers exhibit excellent compatibility with one another such that a thin yet flexible patch is formed and applied which readily adapts itself to the skin. The above teaching of such a thin film layer of PET,

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provides further evidence that the thickness of said layer is a parameter which is capable of being optimized by the ordinarily skilled artisan, absent a showing of evidence to the contrary

Thus, based on the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, alone or in combination, especially in the absence of evidence to the contrary.

All claims have been rejected; no claims are allowed.

### CONCLUSION

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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**CORRESPONDENCE**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey T. Palenik/  
Examiner, Art Unit 1615

/Robert A. Wax/  
Supervisory Patent Examiner, Art Unit 1615